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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,777	09/29/2003	Volkert A. Zeijlemaker	P-10499.00	2479

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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/673,777	Applicant(s) ZEIJLEMAKER ET AL.	
	Examiner John F. Ramirez	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 18, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

After a review of applicant's remarks, all necessary changes to the claims have been entered.

Applicant's arguments filed August 18, 2006 with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection. Therefore, the following office action is provided in order to expedite the prosecution of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14-15, 16-25 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases "wherein the timing information relates to at least one of cardiac therapy delivery and cardiac activity sensing", "based at least in part upon the timing information", "relating to one of the application of an IMD therapy to a patient and the receipt of sensed physiologic signals of the patient", and the words "deleteriously interacting", "temporal", and "temporally" are considered to be new matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15, and 26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

On October 26, 2005, the USPTO published Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility. See:

(http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf).

This guidelines details a procedure for determining patent eligible subject matter. As to claims 1, 10, 14 and 26, the first step in this process is whether the claims fall within one of enumerated categories. In the immediate application, the claims are drawn to a process and an apparatus - a "method and an apparatus of performing magnetic resonance imaging" - and meets this step. However, the analysis does not end here. The next step is whether a judicial exception (abstract ideas, laws of nature, natural phenomenon) is provided in the claim. In the immediate application, claims 1, 10, 14, and 26, clearly includes one of the judicial exceptions in that "receiving timing information from an implantable medical device", "performing the MRI based on the timing information", and the step of "communicating timing information indicative of a timing of the stimulation", are nothing more than abstract ideas which provide no transformation or practical application. While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether it is for a particular application

of the abstract idea. For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomena. To satisfy the requirement of a practical application, the claimed invention must:

(1) transform an article or physical object to a different state or thing; if no transformation, then

(2) the claimed invention must produce a useful, concrete, and tangible result.

Regarding (1) above, the claims do not provide a transformation or reduction of an article to a different state or thing. Grouping equivalent dipoles based on predetermined criterion and solving inverse problems clearly do not transform an article or physical object to a different state or thing. Accordingly, one must then consider whether the claimed invention produces a useful, concrete, and tangible result.

(1) Useful Result

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claim does not provide a useful result in that the claim does not actually solve a problem. It does not appear to be specific as to how the problem is solved and, if solved, it is not specific as to the use of this solution.

(2) Tangible Result

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials

Art Unit: 3737

to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claim clearly does not provide a practical application. The problem, even if solved, is not practically applied to produce a real world result. For example, once the problem is solved, how is this then applied?

(3) Concrete Result

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Regarding the concrete result requirement, the claims do not provide a result that can be assured in that the result can not be substantially repeatable and the process can not substantially produce the same result again.

In view of the above analysis, applicant's claims 1, 10, 14, and 26 are a process and an apparatus of performing magnetic resonance imaging, which includes a judicial exception therein. Upon review of the claim as a whole, there is no transformation nor does the claim produce a useful, concrete, and tangible result. Accordingly, the claim is non-statutory under 35 U.S.C. 101.

Art Unit: 3737

In relation to claims 2-9, 11-13, 15 and 26, depend from claims 1, 10, and 14 respectively and, as such, include the various steps thereof. As discussed above, claims 1, 10, and 14 are a process and an apparatus that provides no transformation of signals and there is no practical application, which is useful, concrete and tangible.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 8-10, 14-16, 22, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al. (US 6,925,328).

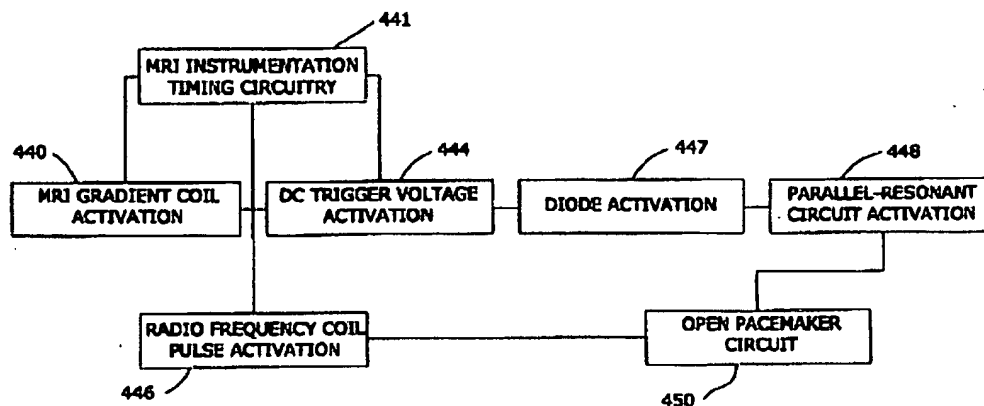


FIG.5

Foster et al. discloses a magnetic resonance imaging (MRI) device comprising: a magnet to generate a magnetic field (col. 1, lines 24-41); an electromagnetic radiation source to apply electromagnetic radiation bursts (col. 1, lines 24-41); an imaging unit to generate images of patient following application of radiation bursts (col. 8, lines 37-55); a receiver to receive information from an implantable medical device (IMD) (abstract); and a control unit to coordinate application of the electromagnetic radiation bursts based on the information (see Figure 5), the information defines a timing of stimulation pulses applied to a patient with the IMD, in which the received information defines a timing of the stimulation applied to the patient by the IMD (col. 7, lines 5- 67).

With respect to claims 8 and 9, Foster et al. shows in Figure 5 performing an MRI includes applying one or more electromagnetic radiation bursts and applying one or more gradient magnetic fields based on the information.

With respect to claims 14 and 15, Foster et al., teaches all the structures as set forth above. The method comprising the steps of: 1) sending information to an implantable medical device (IMD) to define operation of the IMD during MRI; 2) performing the MRI in coordination with operation of the IMD and 3) the information defines a timing for application of stimulation pulses by the IMD would be inherently met by the disclosure.

Claims 6, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Terry et al. (US 6,937,906).

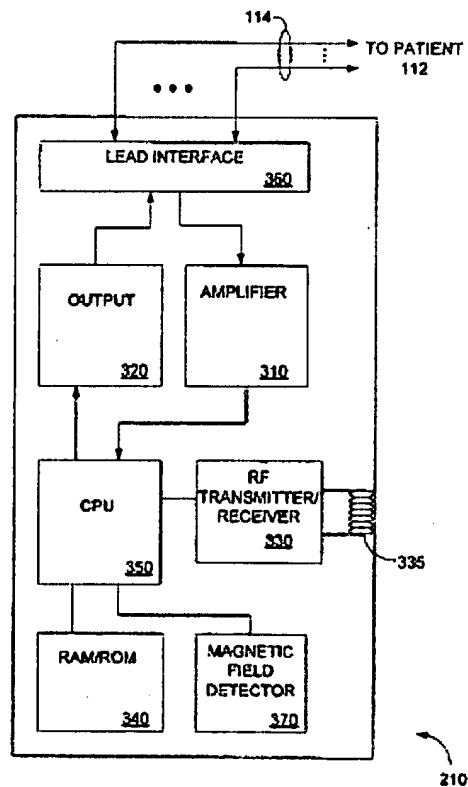


Figure 3

Terry et al. shows in Figures 1-3, an implantable medical device (IMD) (110) with a control unit (col. 3, line 48-50) to coordinate application of magnetic resonance

Art Unit: 3737

imaging (MRI) electromagnetic radiation bursts with operation of an implantable medical device (col. 3, line 48 – col. 4, line 44); and a transmitter (330) to transmit information to the IMD to cause the IMD to operate in coordination with an MRI device (col. 3, line 48 – col. 4, line 44), the medical device comprises a programmer for the IMD (Figure 3) and an MRI system, further comprising stimulating the patient with the IMD to induce an arrhythmia during the MRI (col. 5, line 21- col. 6, line 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 7, 11-13, 17, 18, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. in view of Greatbatch (US 2003/0109901).

Foster et al. teaches all the limitations of the claimed subject matter except for mentioning specifically an MRI system and a pacemaker which collects information of a cardiac cycle, and the received information includes an indication of sensed conditions measured by the IMD, an indication of one or more stimulations applied by the IMD, and the MRI device applies the electromagnetic radiation bursts based on the information.

However, an MRI system and a pacemaker which collects information of a cardiac cycle, and the received information includes an indication of sensed conditions

measured by the IMD, an indication of one or more stimulations applied by the IMD, and the MRI device applies the electromagnetic radiation bursts based on the information is considered conventional in the art by the teachings of Greatbatch (see Abstract and Figure 1).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Foster et al., with the above discussed enhancements would have been considered obvious because such modifications would have provided a stand-alone cardiac stimulating and monitoring system during MRI scanning without operational disruption and without physiological injury to the patient's heart.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3737

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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11/02/06


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